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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,912	01/12/2001	Willem Frederik Van Eelen	BO42358	4846

7590

08/11/2003

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/11/2003

66

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/581,912

Applicant(s)

VAN EELEN ET AL.

Examin r

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 16-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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#### DETAILED ACTION

Claims 1-23 are pending. Claims 16-23 are considered on the merits. Claims 1-15 are withdrawn from consideration as being drawn to a non-elected invention.

#### Election/Restriction

Applicant's election with traverse of Group II in Paper No. 15 is acknowledged. The traversal is on the grounds that the newly presented claims do not lack a special technical feature because the product is now limited to one which is suitable for human and/or animal consumption. This is not found persuasive because contrary to applicants' assertions, Chromiak *et al.* does not have a "hazardous material", that is, an antibiotic in the product which is a tissue culture generated muscle tissue. Thus, even though the intent of Chromiak *et al.* is not the production of food, since it does not use antibiotics in the culture media, it is as suitable for use as food as the instant product. Thus, the product AS CLAIMED is still known in the art.

The requirement is still deemed proper and is therefore made FINAL.

#### Claim Rejections - 35 USC § 112

##### INDEFINITE

Claims 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 used the term "i.e. comprising...". This makes the claim indefinite because it cannot be determined if the phrase is intended to further limit the preceding phrase or is simply an example.

Claim 19 recites "such as" which may be interpreted to either limit the preceding phrase or not.

Claim 21 recites "as such". It is unclear to what this refers.

Claim 21 has "e.g." and "preferably" in the claim. It is unclear if these further limit the preceding phrase or not.

Claim 23 has "e.g." in the claim. It is unclear if these further limit the preceding phrase or not.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 16-21, 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chromiak *et al.*.

The claims are directed to a product consisting of animal cells selected from muscle, stem cell or somite cells in a three dimensional form, produced *in vitro* which is free of fat, tendon, bone and gristle, wherein the product is suitable for human and/or animal consumption.

The references are relied upon as explained below.

Chromiak *et al.* disclose a product consisting of animal muscle cells in a three dimensional form, produced *in vitro*. Since the three dimensional organoid has been produced without the addition of antibiotics (see page 695 last paragraph where no antibiotics have been added to the DMEM and the first paragraph on page 696 where no antibiotics have been added to the DMEM), it appears to be at least as suitable for consumption as the claimed product. Since the intended use of a product is of little patentable weight when considering a product claim, and all of the technical limitations of the product claim have been met, the claimed product is anticipated by the reference.

The product is free of hazardous amounts of growth hormones, antibiotics and have been grown in a medium which incorporates vitamins and minerals, see Gibco Catalog for listing of ingredients in DMEM. Since the product has been immersed and grown in a medium comprising vitamins and minerals, it is reasonably considered to have vitamins and minerals as components of the organoid.

The product of Chromiak *et al.*, since it appears to be produced by the same method as the instant method, would be reasonably expected to have the same texture as the instant product in the absence of evidence to the contrary.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chromiak *et al.*.

The claim is directed to a quantity of the animal cell culture product.

Although the reference is silent with regard to the weight of the product, one of skill in the art could produce any quantity desired. This is an element of experimental design and is well within the purview of one of skill in the art. Mere increase in the mass of a known product is obvious.

Cited as being of interest is JP 2002/191326.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
August 8, 2003